REMARKS

Claims 42-47, 49-52, 55, 57, 59, 61 and 63 are pending upon entry of the above amendments. Claims 42-45 and 50-51 have been amended herein. No new matter has been introduced.

Inventorship

Applicants submit concurrently herewith, an Amendment and Petition to correct inventorship by deleting the following name(s): Kimberly A. Spytek; Li Li; Adam R. Wolenc; Andrew J. Eisen; Xiaohong Liu; Uriel M. Malyankar; Richard A. Shimkets; Velizar T. Tchernev; Steven K. Spaderna; Linda Gorman; Ramesh Kekuda; Vladimir Y. Gusev; Esha A. Gangolli; Xiaojia (Sasha) Guo; Suresh G. Shenoy; Luca Rastelli; Stacie J. Casman; Ferenc L. Boldog; Catherine E. Burgess; Shlomit Rebecca Edinger; Karen E. Ellerman; Erik Gunther; Glennda Smithson; Isabelle Millet; and John R. MacDougall. Each of the above listed inventors' invention is no longer being claimed in the instant nonprovisional application. The remaining correct inventors named on this application are Meera Patturajan and Corine Vernet.

Rejections under 35 U.S.C. §112, second paragraph

Claims 43, 45 and 51 are rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite.

Claim 45 remains rejected as the term "complement" is considered to be vague and indefinite by the Examiner. Applicant respectfully disagrees, however to expedite prosecution of the present application, Applicant has amended claim 45 herein to recite the full length complement. Applicant requests that this rejection be withdrawn.

Claims 43 and 51 are newly rejected as "mature form" is considered to be vague and indefinite because the Examiner finds it unclear as to whether the mature form is directed to a secreted protein or membrane protein.

Applicants respectfully point out that the present specification specifically defines "mature form" as follows:

> An NOVX nucleic acid can encode a mature NOVX polypeptide. As used herein, a "mature" form of a polypeptide or protein disclosed in the present invention is the product of a naturally occurring polypeptide or precursor form or proprotein. The

> naturally occurring polypeptide, precursor or proprotein includes, by way of nonlimiting example, the full-length gene product, encoded by the corresponding gene. Alternatively, it may be defined as the polypeptide, precursor or proprotein encoded by an ORF described herein. The product "mature" form arises, again by way of nonlimiting example, as a result of one or more naturally occurring processing steps as they may take place within the cell, or host cell, in which the gene product arises. Examples of such processing steps leading to a "mature" form of a polypeptide or protein include the cleavage of the N-terminal methionine residue encoded by the initiation codon of an ORF, or the proteolytic cleavage of a signal peptide or leader sequence. Thus a mature form arising from a precursor polypeptide or protein that has residues 1 to N, where residue 1 is the N-terminal methionine, would have residues 2 through N remaining after removal of the N-terminal methionine. Alternatively, a mature form arising from a precursor polypeptide or protein having residues 1 to N, in which an N-terminal signal sequence from residue 1 to residue M is cleaved, would have the residues from residue M+1 to residue N remaining. Further as used herein, a "mature" form of a polypeptide or protein may arise from a step of post-translational modification other than a proteolytic cleavage event. Such additional processes include, by way of non-limiting example, glycosylation, myristoylation or phosphorylation. In general, a mature polypeptide or protein may result from the operation of only one of these processes, or a combination of any of them. (Page 197)

Therefore what applicant intends as "mature form" is clear and does not necessarily pertain to whether the protein is secreted or membrane associated. Applicants request that this rejection be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph, lack of enablement

Claims 42, 46-47, 49, 50, 52, 55, 57, 59, 61, and 63 are rejected under 35 U.S.C. §112. first paragraph as allegedly failing to comply with the enablement requirement

Claims 42 and 50 are considered not enabled as the Examiner contends that one of skill in the art cannot immediately recognize the embodiments which fail to permit translation of the polypeptide in an expression system. The Examiner cites Hatfield US 5,082,767 as describing significant obstacles that remain when one attempts to express a foreign or synthetic gene in an organism. Furthermore, the Examiner states:

> "The translation of a synthetic gene, even when coupled with a strong promoter, proceeds much more slowly than would be expected. And even when the gene is translated in a sufficiently efficient manner, the protein is often inactive or other wise different in properties (failed embodiments) from the native protein. Therefore, one of skill in the art would not know how to predictably make the *claimed invention* without undue experimentation." (Emphasis added)

Applicant respectfully disagrees. With regards to inoperative subject matter the MPEP at 2164.08(b) states:

> "The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made would be inoperative or operative with expenditure of no more effort than is normally required in the art."

Given a specified amino acid sequence, it is elementary to one of skill in the art to determine the limited nucleic acid molecules that would encode it. One of skill in the art would know that a library of such molecules could be made, for example, and transfected into cells or expressed as phage libraries and screened for those that have the protein successfully expressed. This process is entirely routine in the art. Furthermore one of skill in the art can make the claimed invention, that is, *the nucleic acid molecule* by methods within their skill without undue experimentation. The Examiner's comments with regards to challenges in translation, translation efficiency and obtaining active protein are appreciated; however pertain to protein and the method of making a protein, not the claimed invention, namely, nucleic acid molecules.

The Examiner relies upon Hatfield, US 5,082,767 as an example of the state of the art. However Hatfield was filed Feb 27, 1989 and issued Jan 21, 1992 and therefore is not an appropriate reference with regards to the state of the art relevant to the present application which was filed in 2001. Furthermore with regards to the state of the art, even in 1989, Hatfield states:

> "The expression of foreign heterologous genes in transformed organisms is now commonplace. A large number of mammalian genes, including for example, murine and human genes have been successfully inserted into single celled organisms. Standard techniques in this regard include introduction o the foreign gene to be expressed into a vector such as a plasmid or a phage and utilizing that vector to insert the gene into an organism. The native promoters for such genes are commonly replaced with strong promoters compatible with the host into which the gene is inserted. Protein sequencing machinery is widely available that permits elucidation of the amino acid sequences of even minute quantities of native protein. From these sequences, DNA sequences coding for these proteins can be inferred. DNA synthesis is also rapidly developing art, and synthetic genes corresponding to those inferred DNA sequence scan be readily constructed."

Additionally, Hatfield teaches methods for overcoming the limitations known in the art, for example by methods for determining the appropriate codons for any desired translational effect,

particularly for optimizing efficiency of translation. Such methods are available and are within the skill of one in the art at the time the present application was filed.

The MPEP 2164.08 further specifically states:

> "When claims are directed to any purified and isolated DNA sequence encoding a specifically named protein where the protein has a specifically identified sequence, a rejection of the claims as broader than the enabling disclosure is generally not appropriate because one skilled in the art could readily determine any one of the claimed embodiments."

Applicant's claims directed to any isolated DNA sequence encoding Applicant's novel protein, specifically identified as SEQ ID NO:38 is within the skill of one skilled in the art as any one of the claimed embodiments can be readily determined.

Applicants respectfully submit that claims 42, 46-47, 49, 50, 52, 55, 57, 59, 61, and 63 are enabled and request that this rejection be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph, lack of written description

Claim 45 is rejected under 35 U.S.C. §112. first paragraph as allegedly containing subject matter which was not described in the specification is such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, has possession of the claimed invention.

Applicants disagree. Claim 45 has been amended herein to more particularly recite what the Applicants regards as their invention. The claim pertains to a single nucleic acid molecule that is the full-length complement of the polynucleotide SEQ ID NO:37. As such, Applicants believe the claim is clear and fully supported by the specification as filed and respectfully request this rejection be withdrawn.

Rejection under 35 U.S.C. § 102

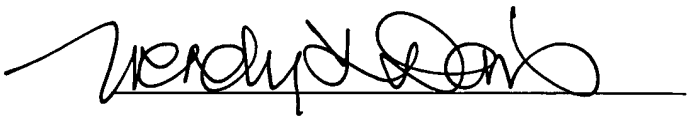
Claims 42, 44-47, 49, 50, 52, 55, 57, 59, 61 and 63 are rejected under 35 U.S.C. §102(b) by the Examiner as anticipated by Oohashi et al. The Examiner notes that the limitation of "a polypeptide of SEQ ID NO:38" has been construed as any polynucleotide with encodes a dipeptide of SEQ ID NO:38.

Applicants disagree. To more particularly point out what Applicants regard as their invention, claims 42-45, 50, 51 and thereby dependent claims 46-47, 49, 52, 55, 57, 59, 61, 63 have been amended herein to recite "a polypeptide SEQ ID NO:38" or "a nucleic acid sequence SEQ ID NO: 37". As such, the claims do not pertain to any dipeptide of SEQ ID NO:37 or 38 and are not anticipated by Oohashi. Applicant respectfully requests this rejection be withdrawn.

CONCLUSION

Applicant respectfully requests that the amendments and remarks made herein be entered and made of record in the file history of the present application. Applicant respectfully submits that this paper is fully responsive and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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